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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,996	11/21/2003	Ning Wei	KCX-742 (19795)	9086

22827 7590 01/12/2007
DORITY & MANNING, P.A.
POST OFFICE BOX 1449
GREENVILLE, SC 29602-1449

EXAMINER	
DIRAMIO, JACQUELINE A	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,996	WEI, NING	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *15-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/13/04; 12/16/04*; 2/28/05; 6/13/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1 – 14 in the reply filed on October 23, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 15 – 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions.

Information Disclosure Statement

The references submitted in the IDS forms were considered by the examiner. However, due to the length and number of references submitted, Applicant is advised to submit a note of relevance for any of the references with outstanding similarity to the instant application.

Claim Objections

Claim 1 is objected to because of the following informalities:

In Claim 1, line 6, the term "a capture **regent**" is recited, which is an incorrect spelling for "reagent."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase "a porous membrane that is in fluid communication with detection probes..." which is vague and indefinite because it is unclear where exactly the detection probes are located.

Claim 1 further recites steps ii) – iv), wherein the test sample is contacted with the scavenging zone, the conjugated detection probes, and the detection zone, however it is unclear how these steps are connected to one another. Does the sample flow from the scavenging zone to the detection zone, wherein the conjugated detection probes are located on the porous membrane somewhere in between the scavenging zone and the detection zone? Further, is it the same test sample that is contacted with the scavenging zone, the conjugated detection probes and the detection zone, or are aliquots taken of the test sample and contacted with the various regions? The claim recitations are vague and indefinite for how the method steps and regions of the assay device are connected.

Claim 1 also lacks a detection step that concludes the method of detecting an analyte in a test sample.

Claim 10 recites the term "said calibration probes," which lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 10 and 12 – 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Buck (US 6,258,548).

Buck teaches a lateral flow test strip and method for detecting an analyte in a test sample utilizing the test strip, wherein the method comprises:

i) providing the lateral flow test strip (flow-through assay device) comprising a porous membrane that is in fluid communication with an indicator reagent (detection probes) conjugated with a specific binding ligand (member) for the analyte, wherein the test strip defines an analyte modulating zone (AMZ) (scavenging zone) and an analyte test zone (ATZ) (detection zone), each of said zones containing an immobilized binding ligand (capture reagent) for the analyte;

ii) contacting said AMZ with the test sample so that a quantity of the analyte equal to a predefined base quantity binds to said immobilized binding ligand at said AMZ;

iii) contacting said conjugated indicator reagents with the test sample; and

iv) allowing the test sample and said conjugated indicator reagents to flow to said ATZ so that said conjugated indicator reagents or complexes thereof bind to said immobilized binding ligand and generate a test (detection) signal, wherein the quantity

of analyte in the test sample in excess of said predefined base quantity is proportional to the intensity of said test signal (see Figure 1; and column 2, lines 35-60; column 3, lines 30-67; column 4, lines 1-67; column 5, lines 17-34; Example 1 and Table 1).

With respect to Applicant's claims 2 – 6, the immobilized binding ligand at both said AMZ and said ATZ comprises a capture antibody, wherein the analyte comprises an antigen, such as hCG (see column 2, lines 35-52; column 4, lines 36-38; column 5, lines 17-34; and Example 1).

With respect to Applicant's claim 7, the test sample contacts the conjugated indicator reagents only after contacting said AMZ (see Figure 1; column 5, lines 17-34; and Example 1).

With respect to Applicant's claim 8, the test strip comprises a wicking pad 14 (sampling pad) that defines said AMZ (see Figure 1; and column 5, lines 17-34).

With respect to Applicant's claim 9, the test strip includes a conjugate pad 18 located downstream from said wicking pad 14, wherein said conjugated indicator reagents are applied to said conjugate pad (see Figure 1; column 5, lines 17-34; and Example 1).

With respect to Applicant's claim 10, the test strip can further include a reference or control line (calibration zone) within which is an immobilized binding partner (capture reagent) that is configured to bind to a labeled control reagent (calibration probes), said control line generating a control signal (see column 6, lines 49-50; column 7, lines 19-56; and Example 1).

With respect to Applicant's claim 12, the conjugated indicator reagents can comprise luminescent compounds, radioactive compounds or colored latex beads (direct visual labels) (see column 4, lines 10-20; and Example 1).

With respect to Applicant's claim 13, the binding ligand (capture reagent) or capture antibody is immobilized in said AMZ (see column 5, lines 17-34 and Example 1).

With respect to Applicant's claim 14, the ATZ or test line is located downstream from said AMZ (see column 5, lines 17-34 and Example 1).

Claims 1 – 7 and 12 – 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Manita (US 6,177,281).

Manita teaches an assay method for detecting an analyte in a test sample, wherein the method comprises:

i) providing a flow-through assay device comprising a porous membrane that is in fluid communication with a labeled substance (detection probes) conjugated with a specific binding member for the analyte, wherein the device defines an antibody-fixed portion (scavenging zone) and a detection portion (detection zone), each of said portions containing an antibody (capture reagent) for the analyte;

ii) contacting said antibody-fixed portion with the test sample so that a quantity of the analyte equal to a predefined base quantity binds to said immobilized antibody at said antibody-fixed portion;

iii) contacting said conjugated labeled substances with the test sample; and

iv) allowing the test sample and said conjugated labeled substances to flow to said detection portion so that said conjugated labeled substances or complexes thereof bind to said immobilized antibody and generate a detection signal, wherein the quantity of analyte in the test sample in excess of said predefined base quantity is proportional to the intensity of said detection signal (see Figures 1-3; column 3, lines 29-62; column 6, lines 5-67; column 7, lines 1-32; column 11, lines 26-37; column 12, lines 55-59; column 13, lines 26-59; and column 14, lines 4-11).

With respect to Applicant's claims 2 – 6, the capture reagent at both said antibody-fixed portion and said detection portion comprises an antibody, wherein the analyte comprises an antigen (see column 5, lines 1-67; column 6, lines 1-9 and lines 41-67; and column 7, lines 1-32).

With respect to Applicant's claim 7, the test sample contacts the conjugated labeled substance only after contacting said antibody-fixed portion (see Figures 1-3; column 6, lines 60-67; and column 7, lines 1-32).

With respect to Applicant's claim 12, the conjugated labeled substances can comprise direct visual labels and luminescent compounds (see column 6, lines 18-34).

With respect to Applicant's claim 13, the antibody is immobilized in said antibody-fixed portion (see column 7, lines 13-32; column 12, lines 55-67; and column 13, lines 1-35).

With respect to Applicant's claim 14, the detection portion is located downstream from said antibody-fixed portion (see Figures 1-3; and column 6, lines 60-67; and column 7, lines 1-32).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buck (US 6,258,548) in view of Harris et al. (US 2003/0162236).

The Buck reference, which was discussed in the first 102(b) rejection above, fails to teach that the signal generated in the control zone (calibration zone) is compared to the test (detection) signal generated in the test zone (detection zone) in order to calibrate the test signal.

Harris et al. teach a method and test strip for measuring the amount of an analyte of interest in a fluid sample, wherein the test strip includes an application point, a contact region, a sample capture zone, and a control capture zone. The contact region contains analyte-binding particles, which bind to and label the analyte of interest. The sample and control capture zones contain immobilized capture reagents specific for the

analyte or analyte-binding particles. When the fluid sample is contacted with the test strip, the fluid sample flows through the contact region, wherein any analyte in the sample can bind to the analyte-binding particles. The sample then flows to the sample and control capture zones, wherein a certain amount of analyte-binding particles bind to and are arrested in both the sample and control capture zones. The signals generated in both the sample and control capture zones are determined and compared in order to determine a ratio between 1) the amount of analyte-binding particles arrested in the sample capture zone, and 2) the amount of analyte-binding particles in the control capture zone. This ratio allows for an increased sensitivity and a more accurate determination of the amount of analyte of interest in a test sample, while also compensating for the variations that result from the dynamic nature of the assays (see paragraphs [0002]-[0007] and [0013]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to compare the signals generated in the test and control zones of Buck as taught by Harris et al. because Harris et al. teach the benefit of determining a ratio that compares the signals generated in a sample capture zone (detection zone) and a control capture zone (calibration/control zone) in order to accurately determine the amount of analyte of interest in a test sample with increased sensitivity, while also compensating for the variations that result from the dynamic nature of the assays.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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